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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 18 2000

WARNING LETTER

With AUTOMATIC DETENTION

VIA Federal Express (Record of receipt requested)

Mr. Stephen Chou
President
ADI Corporation
No. 1, Lane 162, Bu Teu Kung
Kuanghwa Li, Tai Pin City
Taichung Hsien, TAIWAN, R.O.C.

Ref: OC: I1-1878
OC: I1-1861

Mr. Alan Chai
President
ADI Systems (America), Inc.
2115 Ringwood Avenue
San Jose, California 95131

Dear Mr. Chou and Mr. Chai:

This letter is to notify you that the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), hereby disapproves the radiation quality control and testing program for all ADI Corporation's television/computer monitor factories (including but not limited to, those in Taiwan, Thailand and China), effective immediately. We issued a warning letter and program disapproval on July 21, 2000, to the ADI Corporation's monitor factory in Mexico, ADI Systems Mexico, S.A. de C.V., which still remains in effect. These actions are taken under the authority of the United States' (U.S.) Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C – Electronic Product Radiation Control, Section 534(h).

The CDRH is placing all television/computer monitor factories operated by ADI Corporation on program disapproval because of the following:

1) Serious discrepancies were found between data submitted by ADI Corporation and test data from FDA's laboratory, Winchester Engineering and Analytical Center (WEAC),

2) Continuing problems with the lack of responses to FDA's letters concerning an earlier inspection that found similar deficiencies at ADI's factory in Thailand and regarding an earlier WEAC test report,

3) Serious violations of the Act including but not limited to section 538(a)(5) – It is unlawful "for any person (A) to fail to issue a certification as required by section 534(h), or (B) to issue such certification when such certification is not based upon a test or testing program meeting the requirements of section 534(h) or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect."

Chronology of Major Events

On September 21, 1999, an earthquake damaged ADI's factory in Taiwan. ADI representatives at meetings on September 28, 2000 and November 17, 2000, said they no longer manufacture television/computer monitor products in Taiwan but their recent reports still list a factory in Taiwan. Also, ADI representatives, in their reports and in the meetings, said the engineering and design work is still done in Taiwan.

On November 5, 1999, CDRH sent a letter to Mr. James Yu, Quality Assurance Supervisor, ADI Corporation, concerning deficiencies found during an inspection of ADI's factory in Thailand. That inspection was conducted on May 20, 1999, by Messrs. Joseph C. Teixeira and Seth Mailhot from WEAC. They pointed out the deficiencies to factory personnel at the end of the inspection. At the meeting on September 28, 2000, Messrs. James Yu and Adirek Bunyatipanon said that the earthquake in Taiwan on September 21, 1999, severely damaged ADI's factory there. That caused ADI to move to a new facility in Taiwan and, in the process, they lost many documents and some letters were never received. That was their explanation for why CDRH had not received a response. After the September 28, 2000, meeting, CDRH did receive a partial response in the report dated October 17, 2000, by Mr. Neil vanHooydonk of Shotwell & Carr, Inc. (the second consulting firm hired by ADI Corporation to help resolve problems at their factory in Mexico). In his report, Mr. vanHooydonk discussed ADI's methods of sealing controls with RTV and by melting plastic parts on the controls (both of which had problems). Mr. vanHooydonk's report was part of a much larger submittal that also included a videotape of ADI's testing at the Mexican factory and written test procedures (both of these also had problems) and nothing specifically referred to the November 5, 1999, letter or to ADI's factory in Thailand. Finally, at the November 17, 2000, meeting, ADI representatives said that the factory in Thailand would be closed in a few weeks. CDRH representatives requested written confirmation of that but we have not yet received anything in writing about it. CDRH has received only piecemeal responses to the November 5, 1999, letter.

On May 23, 2000, CDRH sent a letter to Mr. James Yu concerning the results of a test of an ADI video monitor at the WEAC laboratory. Those tests confirmed that deficiencies in engineering analysis and testing produced significant differences in the performance data from those reported by ADI Corporation. A low level of x-radiation emission was detected during the WEAC tests. CDRH received a brief response from Messrs. Jack Liao and James Yu, on June 12, 2000, promising a complete response but again no satisfactory response to that letter has ever been received at CDRH.

On June 23, 2000, Mr. Joseph C. Teixeira and Ms. Lesley N. Kerr from the FDA conducted an inspection of the computer monitor company, ADI Systems Mexico, S.A. de C.V., which is operated by ADI Corporation of Taiwan. The purpose of this inspection was to review ADI Corporation's radiation safety quality control and testing program for the certification of compliance of television/computer monitors with the U.S. Federal Performance Standard for Television Receivers, 21 CFR 1020.10. At the end of the inspection, the FDA inspectors reported serious deficiencies in the quality control and testing program including the failure to test these products for x-radiation under Phase III test conditions. In your reports, ADI Corporation had told CDRH they were conducting those tests at all of ADI television/computer monitor factories.

On July 21, 2000, CDRH issued a Warning Letter (copy enclosed) disapproving the testing program for ADI Systems Mexico, S.A. de C.V. for the serious deficiencies in their quality control and testing program for radiation safety of their television/computer monitor products. This July 21, 2000, Warning Letter was addressed to Mr. James Yu, Supervisor, Quality Assurance Department, ADI Corporation.

On July 27, 2000, ADI Corporation submitted a response (received at CDRH on August 11) to the July 21, 2000, Warning Letter. This document was considered inadequate because, among other problems, it did not contain the first consultant's inspection report on the Mexican factory and the training videotape of the x-radiation test procedures. Both of these items were specifically requested in the Warning Letter. ADI was notified on August 30, 2000, of the inadequate response. Between August 11 and September 28, 2000, a series of communications between FDA and ADI transpired. There was no satisfactory resolution of the problems. During this time ADI Corporation submitted the training videotape and first consultant's report, however, CDRH found both to be inadequate and ADI Corporation was notified by telephone before the meeting on September 28, 2000.

On September 28, 2000, Mr. James Yu, ADI Corporation, Taiwan and Mr. Adirek Bunyatipanon, QA Manager, ADI Systems Mexico, S.A. de C.V., met with the staff of the Electronic Products Branch (EPB), Division of Enforcement III, Office of Compliance, CDRH. ADI representatives came to explain and discuss their responses

to the July 21, 2000, Warning Letter, including the first consultant's report and the training videotape. ADI representatives admitted to continuing manufacturing, certifying and shipping products to the U.S. even though the Warning Letter told them not to. In this meeting, CDRH said that the first consultant's report was inadequate and the training videotape had some problems with certain testing and calibration procedures in it. When CDRH questioned ADI representatives about the contents of the tape, the ADI representatives admitted they did not produce the training tape (they had acquired it almost a year ago from another source). At the close of the meeting, EPB requested a sample video monitor, model SM-740, for further analysis by the FDA's laboratory, WEAC.

On November 17, 2000, a second meeting was held at the request of Mr. Neil vanHooydonk, of Shotwell & Carr, Inc., a second consulting firm retained by ADI Corporation. The meeting included Mr. James Yu of ADI Corporation, Mr. Jack Liao of ADI Corporation, Mr. Adirek Bunyatipanon of ADI Systems Mexico, S.A. de C.V., Mr. Alan Chai, President of ADI Systems, Inc. (America), Mr. Jon Parsons, Attorney for ADI Systems, Inc. (America), Mr. Edwin Spievack, General Counsel, and Mr. Neil vanHooydonk, Shotwell & Carr, Inc. and the staff members of EPB. In this meeting, CDRH questioned ADI Corporation's inadequacies in your engineering analysis and test procedures. Based upon WEAC's test results, EPB staff requested further analysis and testing by ADI. The participants also discussed the problems of ADI's continuing manufacturing, certifying and shipping television/computer monitor products to U.S. CDRH raised the question of what ADI proposed to do about the units which were falsely certified. In the meeting, ADI Corporation claimed that only approximately 3,328 computer monitors were manufactured and shipped to U.S. after the July 21 Warning Letter, however CDRH said that those numbers appeared too small because the FDA's Otay Mesa Resident Post reported that ADI Systems (America), Inc. of San Jose, CA, continued to file electronic import entries for the past several months.

On November 19, 2000, three days after the meeting, Mr. Neil vanHooydonk contacted CDRH and said that the actual number of computer monitors shipped to the U.S. is much larger than what ADI Corporation stated at the November 17 meeting.

On December 8, 2000, Mr. vanHooydonk submitted ADI Mexico shipping information, which showed that the Mexican factory shipped 59,757 computer monitors into U.S. after July 21, 2000.

Conclusion

This disapproval of the testing program means that all of ADI Corporation's television/computer monitor factories are prohibited by Sections 534(h) and 538 of the Act from:

1. certifying the electronic products manufactured under the disapproved testing program,

2. introducing or importing products into U.S. commerce which bear false and misleading certification, that is, products certified under the testing program which has been disapproved, and

3. introducing or importing into the U.S. commerce any product which does not have the certification label permanently affixed to the product, as required by 21 CFR 1010.2.

Under Section 536(a) of the Act, FDA may refuse entry or importation into U.S. commerce of any electronic product if it appears that the product fails to comply with the applicable standards, or the manufacturer's testing program has been disapproved. Therefore, all of ADI Corporation's television/computer monitor factories are being placed on the import detention list and their products will be automatically detained at port of entry until the quality control and testing program disapproval is rescinded.

The FDA may initiate regulatory action against any person who violates Section 538, including an injunction and/or imposition of civil penalties as provided for in Section 539 of the Act. Persons failing to correct violations are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000. This Act also prohibits anyone, including the importer, from failing to make any report required pursuant to Section 537(b) or to furnish or preserve any information required pursuant to Section 537(f).

Under 21 CFR 1005.20 and Section 536 of the Act, the owner or consignee of products denied entry shall have an opportunity to present views and evidence that the products comply with the Federal Performance Standard for Television Products, 21 CFR 1020.10.

Resolution

To resolve this matter, you must submit a written response to each item above such that CDRH can determine that all ADI factories are in compliance with the Act, that the subject products comply with the Federal Performance Standard for Television Receivers, 21 CFR 1020.10, and that the testing program is in accord with good manufacturing practices. ADI Corporation must also, under 21 CFR 1002.10, submit to CDRH updated product reports for all active chassis families. Those reports must contain the information specified in 21 CFR 1002.10(a) through (j), and all the corrective actions. In addition, CDRH may require other information reasonably necessary to establish that the products comply with the standard and to enable CDRH to carry out the purposes of the Act. Under 21 CFR 1002.10(k), CDRH requests the following additional information:

1. A list of all of ADI Corporation's active television/computer monitor product factories, their addresses, telephone and facsimile numbers, and a contact person's name at each factory.

2. The radiation quality control and testing program in each ADI factory must be inspected by an independent consultant or a firm who will observe the actual radiation quality control and testing procedures and compare with those reported in ADI's up-dated product reports. The independent consultant's inspection reports should be furnished along with any response concerning this program disapproval.

3. ADI Corporation is to provide CDRH with an adequate training videotape of the Phase III x-radiation testing procedures, including (a) equipment set-up (volt meter, ammeter, input line voltage meter, etc.), the x-radiation survey meters (William B. Johnson TVX-1B, and Victoreen 440 RF/D or equivalent), (b) actual procedures performed on a television receiver or computer monitor including introduction of the worst component failure selected for the test, user and service controls adjustments, test pattern used, measurement of the high voltage and beam current, B plus voltage, operational checks of hold-down safety circuit, daily operational check and correct handling of the qualitative and quantitative x-radiation survey meters, scan patterns, data to be noted and recorded on the final test record, tolerances and rejection limits, and procedures to be followed in case any reading is out of tolerance or over the limit. If some controls are sealed to achieve compliance with the standard, the videotape should show how the technician checks the effectiveness of the sealed critical controls using his fingers, or small tools such as a screwdriver or small knife.

   Step-by step instructions during Phase III x-radiation testing must be in English on the videotape. Since ADI Corporation has factories in different countries using the same quality control and testing procedures, the firm must also make duplicate copies of the videotape using different languages so they can be used for training purposes.

4. Because problems were found during all inspections of ADI factories, we are concerned that all factories have similar quality control problems. Therefore, we are requiring ADI Corporation to conduct immediate audits followed by annual audits of the radiation quality control and testing program in all of your television/computer monitor factories to ensure that these procedures and documents are effectively implemented. Please submit a copy of your corporate audit plan and confirm that the audits of the radiation quality control and testing program will be conducted for all of the factories and provide the name(s) of the individual(s) who will be responsible for conducting each audit and the dates of the audits.

The CDRH will advise you whether your submittal is satisfactory and when introduction of certified products into U.S. commerce may resume from the ADI factories. A copy of this letter will be posted on the FDA's world wide web home page under Monthly Import Detention List and Warning Letters: http://www.fda.gov.

Within 15 days, please submit your response to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, (HFZ-342), Division of Enforcement III, 2098 Gaither Road, Rockville, Maryland 20850. In your response, please reference cases I1-1861 and I1-1878. If you have any questions, you may contact Dr. Edward Dawson, of my staff at (301) 594-4654, or by facsimile at (301) 594-4672.

Sincerely yours,

Gladys Rodriguez for.

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: Copy of July 21, 2000, Warning Letter